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Altera Law Group, LLC 220 S 6 St Suite 1700 Minneapolis, MN 55402			EXAMINER GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/870,321

Applicant(s)

LEHMANN, VOLKER

Examiner

Brian R. Gordon

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-18-07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted amended claims 41-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are have been amended to directed to an analysis method for a medium rather than originally claimed method of taking up (aspirating) a medium. The previously examined method of taking up did not require a liquid to be present/provided or any determining step as claimed. Furthermore it is unclear how the method can be referred to as a method for analyzing when there is no analysis step provided in the claim.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

As to applicant arguments directed to the withdrawn claim 47, original claim 7 was not directed to a pump controller as asserted. See claim sets (01/18/02; 04/15/02):

7. Arrangement according to Claim 6, having an analysis chip for analysing the first medium taken up into the capillary device.

Even if the claim were directed to a pump controller, applicant admits that the "control measure" is a different feature (that was not previously examined) than the pump controller. Likewise, the method steps of claim 48 were not previously examined and are different from those of claim 41.

The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

2. Applicant's arguments filed December 18, 2007 have been fully considered but they are not persuasive.

Applicant has amended claim 1, to include the phrase that the pump is configured to produce a negative pressure. The additional phrase does not add any additional structure to the pump or change the interpretation of the claim. As previous explained since no specifics are provided as determined what a value applicant considers equivalent to such a negative pressure, then the only structural requirement of pump is that it be capable of producing a negative pressure. See previous Office Actions for a detailed explanation.

Applicant has also amended claims 37-39 to incorporate the phrase "the apparatus is configured such that". As previously stated the phrase does not add any additional structure or further structural limitations to that of the prior version of the claim. The previous interpretation is still given to the claim. It is unclear what structure provides for such configuration. It is unclear if the device has a structural element (computer, controller, logic controller, or any other electrical component) that uses the equation and inputted data to calculate the pressure or any of the other variables of the equation. Or on the other hand, does an operator use the device and other instrumentation to make such manual calculations. The claim as drafted does not require the calculation/determination to be done by the device or by an operator or other

outside calculating device. It is only required that one can use such an equation for such calculations which is not a structural limitation of the structure. One can choose to use numerous equations to make various measurements, such equations do not limit the device. The phrase as incorporated in claims 38 and 39 simply means the device has the capability of taking up/aspirating a liquid and gas, respectively.

It should be noted that the additional clause "for taking up the medium to be analyzed" is not further structurally limiting but is directed to the intended use of the pipette. It is only required that the pipette be capable of aspirating a "medium" (non-specified substance). As to what one intends to do or with the medium is not a structural limitation of the apparatus/pipette.

In view applicant's remarks directed to a "given radius" is not intended to give any specific dimensions, then the only structural requirement is the diaphragm have one pore with a radius.

As to applicant's remarks directed to the critical pressure, the examiner maintains his previous interpretation of the claim. Since no specified values are given, the structural requirement of the pump is that it be capable of producing a negative pressure. Adequate factors (those previously given by the examiner) can be freely chosen by an operator such that the negative pressure produced by the pump overcomes a critical pressure (as broadly defined by applicant). As to the examples in the specification referenced by applicant, it should be noted that the claims are read in light of the specification. However, limitations disclosed in the specification, but not positively claimed in the claims are not read into the claims. If applicant intends for any

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specifics related to such examples to be considered as limitations, those limitations must be specifically and positively claimed. Furthermore the last specification submitted on 01/18/02 does not contain paragraph numbers.

As to the prior art rejections, applicant admits the examiner's about the dependency of the broadly recited "critical pressure" is dependent upon a number of factors. However applicant still attempts to argue the broadly defined negative pressure as recited in the configured such phrase in combination with the specification paragraphs [0099] and paragraphs [100] is sufficient to overcome the rejections. The examiner respectfully disagrees and maintains the previous position of the Previous Office Action. Furthermore, the paragraphs of the specification are not limitations of the claim. The claim is broad. As such the previous interpretation of the Previous Office Action (Item 11) and that recited herein is hereby maintained.

Applicant asserts the examiners interpretation is incorrect and states:

While any pump capable of producing a negative pressure might be able to produce a pressure that does not go below the critical pressure for some extant liquid, it is not necessarily configured to produce a pressure that does not go below the critical pressure **for the specific liquid** that is present at the pore (which has a given radius). Thus, for any given liquid and pore radius, it is possible, according to the invention, to determine a critical pressure.

It should be noted that applicant's claim does not recite a specific liquid. The liquid referenced in applicants claim can be any liquid including the same extant liquid applicant recognizes that can be applicable to any pump. Furthermore, as previously restated "a given radius", simply means the pore has a radius.

For reasons given herein above and the incorporation of the reasons of the Previous Office Action, the previous rejection of claims 35-40 are hereby maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The equation of claim 37 is not further limiting of the structure, but state how one intends to calculate the critical pressure (see above explanation in Response to Arguments).

Claim Interpretations

5. For the purpose of examination, a system comprising an aspirating or vacuum device capable of aspirating a liquid or gas and including a porous structure (filter, frit, membrane, disc with a hole/aperture, etc.) with a pore having a radius and pump capable of producing a negative pressure is considered equivalent to the device as claimed by applicant.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bjorkman, US 4,642,220.

Bjorkman discloses a device for carrying out an analysis method. The device includes vessels 2 (pipettes) and the recesses 6 when the reaction vessels 2 are placed

in the rack. In this way there is formed a plurality of chambers 8, which upwards are delimited by the porous bottom elements 3. Downwards the chambers 8 are connected to the channel 4. By using the connecting nipple 5, the channel 4 may be connected to a pressure regulating system (controller/mechanical control unit 25), e.g. to a suitable pump system for controlling the pressure of the chambers 8.

FIGS. 2 and 3 show two different types of reaction vessels, both of which have a porous bottom element 3. In addition thereto the vessel of FIG. 3 has a filter 9, which is applied to and covers the pores of the bottom element 3. For aqueous liquid phases the preferred filter is hydrophilic, particularly a three dimensional depth filter.

We have found that hydrophobic membranes with pore sizes from about 1μ to 20μ are useful for the reaction vessels shown in FIG. 2, especially when biospecific reactions are involved. It is suitable to work with pressure differentials between 100 and 500 Pa when using these types of porous bottoms (column 2, line 58).

8. Claims 35-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Moulton US 5,851,491.

Moulton discloses a filter (diaphragm) for a pipette tip is provided, comprising a plurality of vertically-oriented cylindrical micro fibers cohesively bundled in adjoining columns which are composed of a core of an autoclavable material and an outer coating of a hydrophobic material. The micro fibers are packed together such that each micro fiber is compressed against the other fibers and the inner surface of the pipette tip. The compression of the fibers creates vertically-oriented pores interstitially between the micro fibers, each pore having a pore size at various points within the filter (abstract).

Filter 30 comprises a plurality of cylindrical micro fibers 44. Referring to FIGS. 3 and 4, micro fibers 44 each comprise a core 46 of an autoclavable material and an outer coating 48 of a hydrophobic material. In a first preferred embodiment, core 46 is formed of polypropylene and outer coating 48 is formed of polyethylene.

Pipettor 22 may be any suction device capable of drawing fluid 26 into pipette tip 12 in incremental amounts, including volumetric pipettors, elastic bulbs, bellows, or suction pumps.

9. Claims 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kitajima et al., US 6,225,130.

Kitajima et al. disclose a method of preparing a serum sample from whole blood without destroying blood cells, and thereby, of obtaining highly reliable analytical values. The inventors found that, there is a critical value between the insertion speed of a serum suction nozzle into a vessel and a suction pressure, and a blood serum sample can be obtained without destruction of blood cells by sucking the blood serum while keeping the suction pressure under the critical value (Summary of Invention).

The holder body 10 (pipette) is made of high-impact polystyrene resin, and has a glass fiber filter chamber 11 for containing the glass fiber filter 30 and a microporous membrane chamber 12 for containing a polysulfone microporous membrane as the microporous membrane 40 above the glass fiber filter chamber 11. The microporous membrane has a diameter greater than the glass fiber filter chamber, and the periphery of the microporous membrane 40 is nipped by the step portion 19 formed on the boundary between the glass fiber filter chamber 11 and the microporous membrane

chamber 12 and the bottom of the cap 20 so as not to form a leakage without passing the blood filtering material.

As disclosed in the examples suction was carried out by using a peristaltic pump at a suction pressure (pressure difference) of 300 mm Hg at the maximum for a suction period of 15 seconds.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
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brg